

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-R-0004
CUSTOMER NUMBER: 80

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Virion Systems Inc
9610 Medical Center Drive
Suite 100
Rockville, MD 20850

Telephone: (301) -309-1844

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3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Cotton Rats	3292	6262	18	0	6280
Sigmodon					
hispidus					
Sigmodon					
reventor					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer, or equivalent official)

(b)(6), (b)(7)c

DATE SIGNED

10/18/07

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10/16/07

The facility and all aspects of the program are consistent with the PHS Policy, the Guide, and applicable Animal Welfare Regulations with the following exceptions:

Four departures from current animal welfare regulations are approved by the IACUC.

1. Rodents experiencing difficulty obtaining feed suspended in a wire bar lid or masticating biscuits are provided feed/fines or moistened feed on the floor of the cage. The committee approved this exception to the Animal Welfare Regulations (AWRs) on June 2, 2003.
2. Waste that is or may be perceived to be contaminated by biohazards is disposed of using Medical Pathological Waste boxes which remain uncovered until sealed for incineration. The committee approved this exception to the AWRs on June 2, 2003.
3. To produce transgenic cotton rats Animal Study Proposal (ASP 65), surgery must be conducted under a microscope. The microsurgical instruments are sanitized by immersion in 70% ethanol for at least ten minutes, and then air drying or rinsing them with sterile water before use. The tips of the microsurgical instruments are extremely fine. Steam sterilization would ruin the instruments by causing the delicate tips to become brittle and break rendering them unable to grasp tissue properly. Ethylene oxide or gas sterilization is not available. AWRs require sterile instruments be used. Ethanol will not kill spores and, therefore, does not constitute a means of sterilization. The instruments will be cleaned, sanitized, and stored in a manner that minimizes the risk of contamination by spore forming bacteria. Sanitization by immersion in 70% ethanol in lieu of sterilization presents minimal risk to the cotton rats. The committee approved this exception to the AWRs for ASP 65 on November 1, 2004.
4. Use of the non-pharmaceutical grade anesthetic Avertin was approved in Virion ASP 65. Avertin will not be used as the primary choice of anesthesia but will be used as a back-up. The chemicals used to make Avertin are not pharmaceutical grade, therefore literature has been reviewed on using Avertin in mice and drug trials have been performed on cotton rats applying those principals to prove Avertin can be used successfully in cotton rats as well as mice. The findings were that Avertin works well, as an anesthetic in cotton rats. It would be used for vasectomizing male cotton rats and for embryonic transfer in the female cotton rat. We also wish to note there were no adverse reactions and/or deaths caused by using Avertin as an anesthetic in cotton rats. However, the large dose size to obtain the desired level of anesthesia makes this type of anesthesia a better selection for a "back-up" anesthesia. Here we also wish to note that the cotton rats in the anesthesia trials showed no adverse reactions



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or discomfort due to the volume of Avertin given intraperitoneally. The preparation and storage of the chemicals that are used to make Avertin are strictly controlled to prevent chemical degradation before and after mixing, so there will be no undesirable effects due to chemical break down. The committee approved this exception to the AWRs for ASP 65 on November 1, 2004. The exceptions were also used as a refresher training for the IACUC members on 10/15/07.

Sincerely,

(b)(6), (b)(7)c

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-R-0004

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2. Number 0 of animals used in this study.

3. Species (common name) Cotton Rat of animals used in the study.

4. Explain the procedure producing pain and/or distress.

No Cotton Rats on study at Virion Systems, Inc. were found needing to be listed Column E. This was for the reporting period of 10/1/06 - 9/30/07, and was reviewed by the Virion Systems, Inc. IACUC Committee.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____